

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Date: October 28, 2005

Khalid Raja, et al.

Examiner: Paul Shanoski

Serial No.: 10/692,363

Art Unit: 3763

Filed: October 22, 2003

Conf. No.: 9378

Attorney Docket No.: ACMI-2.006.US

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For: FLUID DELIVERY SYSTEM FOR USE WITH A
SURGICAL PUMPING UNIT

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Trace Brooks
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Date of Deposit: 8-8-06

REQUEST FOR CORRECTED PATENT APPLICATION PUBLICATION
UNDER 37 CFR 1.221(b)

Sir:

Applicant hereby requests that a corrected patent application publication be made for US2006/0122576A1, published on June 8, 2006 due to an error made by the Office. The specification amendments filed on October 22, 2003, and recorded in the PAIR system on the same date, are not evident in the publication. Specifically, the domestic priority data as claimed by applicant is missing from the publication cover sheet. This exclusion constitutes a "material mistake" and qualifies this matter for republication under 37 CFR 1.221(b).

Enclosed are the following:

1. Copy of Applicant's Preliminary Amendment submission of October 22, 2003, identifying line and pages numbers from the originally filed application.
2. Marked-up copies of the published application pages indicating the missing information.

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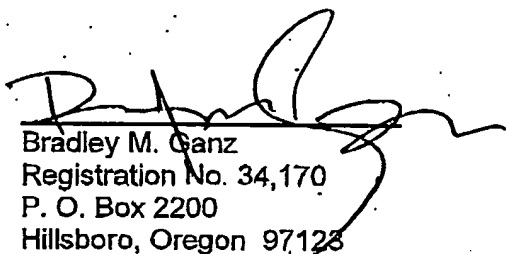
According to 37 CFR 1.221(b), this request is being filed within two months from the publication date of June 8, 2006.

Applicant understands that no fee is required for this request. If, for any reason, a fee is due, the Commissioner is hereby authorized to charge any fees, or underpayments, or to credit any overpayments, to the undersigned attorney's Deposit Account No. 50-1001.

Respectfully submitted,

Date:

8/8/06



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(43) Pub. Date: Jun. 8, 2006

(54) FLUID DELIVERY SYSTEM FOR USE WITH
A SURGICAL PUMPING UNIT

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(21) Appl. No.: 10/692,363

Related U.S. Application Data
(60) Provisional
application no. 60/291,583
filed on May 16, 2001

PCT

(22) Filed:

~~Oct 22, 2003~~ May 16, 2002
(86) PCT No. PCT/US02/15729
Publication Classification

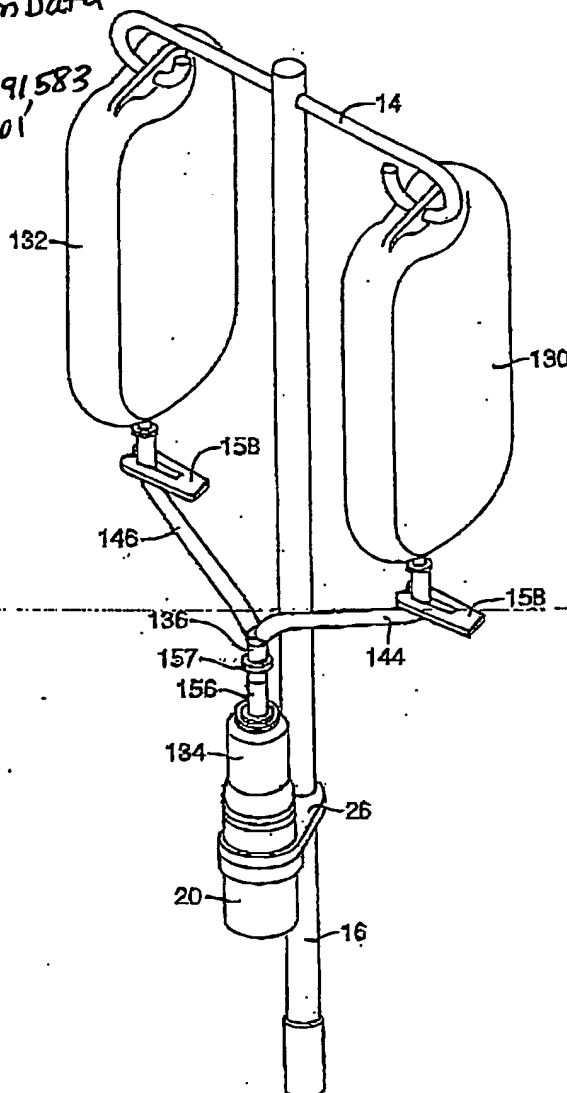
(51) Int. Cl.

A61K 9/22 (2006.01)

(52) U.S. Cl. 604/890.1; 604/80; 604/250;
604/249

(57) ABSTRACT

A surgical irrigation system is provided in which a novel system of connecting and/or supporting a pump to a fluid source reduces the possibility that the pump will become disconnected from the fluid source by requiring that the pump be supported by a support to establish fluid connection.



COPY

US 2006/0122576 A1

Jun. 8, 2006

is the U.S. National Phase of International Patent Application No. PCT/US02/15729, filed May 16, 2002, and

FLUID DELIVERY SYSTEM FOR USE WITH A SURGICAL PUMPING UNIT

[0001] This invention claims the benefit of co-pending U.S. Provisional Application No. 60/291,583, entitled Fluid Delivery System For Use With A Surgical Pumping Unit, filed May 16, 2001, the entire disclosure of which is incorporated by reference as if set forth in its entirety for all purposes.

BACKGROUND OF THE INVENTION

[0002] This invention relates to a system for providing fluid to a surgical site inside a body and in particular this invention relates to a connection system for connecting a pump or other device to a fluid source to supply fluid to the surgical site.

[0003] The use of surgical irrigation systems is known in the art. Such systems typically comprise an irrigation liquid source and a handpiece which has an inlet port connected to the irrigation liquid source, and an outlet port connected to, for example, a probe extending to an operative site within a body. Typically, a plastic bag containing irrigation fluid is suspended from an IV pole and is connected to the handpiece through a pumping device connected to the fluid bag through a tubular spike.

[0004] One example of such a system is disclosed in U.S. Pat. No. 5,484,402, which issued to Saravia et al. on Jan. 16, 1996, the disclosure of which is hereby incorporated by reference for all purposes. Saravia et al. disclose a surgical irrigation system that includes a self-contained pumping unit remotely located from the handpiece to pump irrigation liquid to the handpiece, into the protruding hollow tip, and to the surgical site. The remotely located pumping unit comprises a power supply (i.e., a battery pack), which is activated by an electrical switch in the handpiece. Therefore, the self-contained pumping unit must be connected to the switch in the handpiece by running cumbersome electrical cable along the flexible tubing that connects the pumping unit to the electrical switch on the handpiece. Additionally, the pumping unit is directly connected to the fluid bag by a tubular spike connector that is connected to a luer-type connector on the fluid bag. The pumping unit may be suspended from the bag simply by the interconnection of the respective connectors or may be supported by a bracket. This system is limited in its arrangement since the pumping unit must be directly connected to the fluid bag. This creates a potentially hazardous situation. For example, some surgical rooms have limited space available for surgeons and other hospital personnel to move about. This increases the chance that the pumping unit might be bumped or knocked from its connection with the fluid bag resulting in a dangerous interruption in the delivery of fluid to a patient and creating unsanitary and/or unsafe operating room conditions. This is particularly true when the pumping unit is suspended from the fluid bag and not held in the bracket.

[0005] Another system is disclosed in U.S. Pat. No. 6,176,847, issued to Humphreys, Jr. et al. on Jan. 23, 2001, the disclosure of which is hereby incorporated by reference for all purposes. Humphreys, Jr. et al. disclose a surgical irrigation system that includes a fluid flow sensor device including a fluid accelerator to increase fluid flow to a surgical handpiece. The flow sensor device is directly connected to and supported from a fluid bag but may be

adjustably fixed and supported on a vertical IV pole. While this system has proven effective, the present invention provides improvements in the construction and arrangement of irrigation system components.

SUMMARY OF THE INVENTION

[0006] The present invention overcomes the problems described in the prior art surgical irrigation systems by providing novel systems and methods of connecting the pump or other fluid accelerating device to the fluid source.

[0007] The present invention provides a surgical irrigation system in which the pump must be supported in order to maintain its fluid connection with the fluid source. The system includes novel systems of connecting the pump to the fluid bag that reduces the chance that the pump will become disconnected from the fluid bag by requiring that the pump be supported and not suspended from the fluid bag. The present invention further allows the pump to be located a various positions so that it can be moved out of the way of surgeons or other hospital personnel further reducing the chance that the pump will be knocked from its connection to the fluid bag.

[0008] The present invention further provides means for automatically discontinuing fluid flow delivery if the pump is not properly supported for use.

[0009] In one embodiment the pump is connected to a fluid bag by at least one flexible tube. The flexible tube may be connected to the pump by a variety of connectors and/or fittings to accommodate a variety of arrangements. Plural flexible tubes may be connected to the pump for connection to one or more fluid bags.

[0010] In another embodiment the pump includes a switch that completes an electrical circuit to supply power to the pump motor only when the pump is located and/or supported by a support. If the pump is not located in the support switch remains open and no power is supplied to the pump motor and no fluid will flow to the handpiece.

[0011] In another embodiment the pump is connected to the fluid bag by a connector that includes a valve that closes and prevents fluid flow if the pump is not supported in a support.

[0012] In yet another embodiment the pump is connected to the fluid bag by a connector that is supported by a bracket. The pump is constructed and arranged so that it cannot be connected to the fluid bag other than through the connector which itself is supported.

[0013] In still another embodiment the pump is connected to the fluid bag by a connector in which fluid flow is blocked until a user activates a release mechanism to start fluid flow.

[0014] These and other embodiments are described in more detail in the following detailed description and the figures.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] FIG. 1 is a schematic drawing of a representative surgical irrigation system of the present invention.

[0016] FIG. 2 is a schematic cross-section of a preferred pump for use with the present invention.

wall 240 of retainer housing 222 to close ports 234 and 236 as seen in the closed position of FIG. 24.

[0093] FIG. 26 shows a system in which pump 20 is connected to a fluid bag 250 that is suspended inside a carriage 252 hung from a standard arm 14. A standard spike 254 is inserted into fluid bag 250 having a standard outlet. Spike 254 is then connected to an inlet fitting 258 on pump 20. Fluid bag 250 is positioned within carriage 252 so that a gap 260 exists between arm 14 and fluid bag 250 so that it will pull away from pump 20 if fluid bag 250 is hung directly and independently from arm 14.

[0094] FIGS. 27-32 show an alternative system of supporting a pump connected to a fluid bag. In this embodiment, an L-bracket 300 is provided to hook onto a standard pole. The L-bracket 300 includes an elongate body 302 that adjustably supports an extension member 304 that supports pump 20. In FIG. 27 extension member 304 is adjustable along the length of body 302 to connect to various size fluid bags. FIGS. 28 and 29 show one embodiment of a support member 305 to which a fluid bag may be supported by inserting a pin 306 (FIG. 29) in one of a number of holes 308 in support member 305. Alternatively, a fluid bag may be hung from hooks or prongs along body 302. Pump 20 is connected to the fluid bag by a spike 312. Extension member 304 includes a connector portion 310 to which both pump 20 and spike 312 are attached by a threaded connection. Impeller housing 314 includes outer threads 316 for threaded engagement with inner threads 318 on spike 312. Spike 312 further includes outer screw threads 320 for threaded engagement with inner screw threads 322 on connector portion 310.

[0095] In an alternative embodiment of FIG. 33 connector portion 310 may include outer screw threads 324 for threaded engagement with inner screw threads 325 on spike 312 so that spike 312 is screw threaded onto the top of connector portion 310. Impeller housing 326 includes outer threads 327 for threaded engagement with inner screw threads 328 located in connector portion 310.

[0096] Instead of screw threads the pump may be connected to the L-bracket extension 340 by a bayonet-type lock as seen in FIG. 34. In this embodiment, spike 342 is connected to a top end of the impeller housing 344 by a press fit with an O-ring 346 providing a fluid seal. Impeller housing 344 is located within extension 340 so that spike 342 extends through an opening 348 for connection with a fluid bag. Impeller housing 344 is then rotated so that a protrusion 350 is received in a lock opening 352 in extension 340.

[0097] In this embodiment the L-bracket and spike 342 are re-usable but must first be sterilized before each use. However, the pump and spike 342 may also be a disposable as a single use entity. In either case, the pump is not capable of attaching to the fluid bag without the use of the L-bracket.

[0098] FIG. 35 shows another embodiment in which a pump such as, for example, is directly connect to a fluid bag and is supported by a special fitting. An outer fitting 360 is securely attached to impeller housing 362 so that spike 364 extends through and out of outer fitting 360 for connection with a fluid bag. Outer fitting 360 includes an inner member 366 with gripping teeth 368 to frictionally grip the outside of fluid bag outlet 365 when spike 364 is attached thereto.

In this embodiment, the pump is suspended from the fluid bag but is held by the frictional engagement between inner member 366 and the fluid bag outlet.

FIG. 36
[0099] FIG. 37 shows another embodiment in which the pump is suspended from the fluid bag by a spike 380. However, fluid flow is not automatically started upon spiking the fluid bag. Spike 380 includes a valve lever 382 that is normally biased to a closed position by an extension spring 383. After spike 380 has been inserted into the fluid bag the fluid bag presses down on valve lever 382 against the bias of extension spring 383 to the position shown in phantom in FIG. 37 to open the fluid passageway in spike 380 to allow fluid to flow from the fluid bag. Fluid flow will only be facilitated when valve lever 382 is moved down by the fluid bag. When the fluid bag is removed valve lever 382 is closed by extension spring 383.

[0100] Alternatively, spike 380 may be non-tubular and may sealingly engage the fluid bag so that the pump hangs independently from the fluid bag by spike 380 and valve 382 may be part of impeller housing.

FIGS. 38 and 39
[0101] FIGS. 38 and 39 show another embodiment in which the pump is suspended from the fluid bag by a spike 400. Retainer housing 402 slidably supports spike 400 that includes upper and lower detent recesses 404 and 406 for selective engagement with detent 408 on retainer housing 402. A stopper 412 is fixedly located within retainer housing 402. After spike 400 is connected to the fluid bag spike 400 is moved into the sealed position shown in FIG. 38 in which detent 408 is located in upper recess 404. In this position, stopper 412 closes fluid passageway 414 to block fluid flow. The user is then required to pull the pump downwardly to move detent 408 into lower recesses 406 to open passageway 414.

FIG. 40
[0102] FIG. 40 shows an alternative embodiment of supporting the pump from a fluid bag 450. In this embodiment, spike 452 includes a retainer fan 454 that is retracted until spike 452 is inside fluid bag 450. Spike 452 has an outer diameter that is less than the inner diameter of fluid bag outlet 456 so that there is clearance between the walls of fluid bag outlet 456 and spike 452. In use, the user will spike fluid bag 450 while retainer fan 454 is retracted. After spiking fluid bag 450, retainer fan 454 is opened by an actuator 458 on impeller housing 460 so that retainer fan 454 moves up into fluid bag 450 and opens. Retainer fan 454 will be completely open when it passes fluid bag outlet 456. The user then releases the pump which will drop under its own weight so that retaining fan 454 can rest on the inside of fluid bag 450. The fluid bag outlet 456 includes a seal 462 to prevent fluid loss.

FIGS. 41 and 42
[0103] FIGS. 41 and 42 show one embodiment for actuating retainer fan 454. Retainer fan 454 includes spring-biased arms 460 that are normally closed as seen in FIG. 41. To open retainer fan 454 actuator 458 is moved to the left as shown in FIG. 42 so that bottom portion 462, which in the closed position rests on upper surface 464 of actuator 458, moves downward along surface 468 to rest on surface 466. As bottom portion moves arms 460 are biased open (FIG. 42) to rest or engage inner surface 470 of fluid bag 450.

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 CFR 1.63(b))

Attorney Docket No.	ACM-2.006US
First Inventor	Khalid Raja
Title	FLUID DELIVERY SYSTEM FOR
Express Mail Label No.	EV329254543US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

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- ☐ Applicant claims small entity status.
See 37 CFR 1.27.
- ☒ Specification [Total Pages: 20]
(preferred arrangement set forth below)
 - Descriptive title of the invention
 - Cross Reference to Related Applications
 - Statement Regarding Fed sponsored R & D
 - Reference to sequence listing, a table, or a computer program listing appendix
 - Background of the invention
 - Brief Summary of the invention
 - Brief Description of the Drawings (if filed)
 - Detailed Description
 - Claim(s)
 - Abstract of the Disclosure
- ☒ Drawing(s) (35 U.S.C. 113) [Total Sheets: 30]
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Signed statement attached deleting inventor(s)
name in the prior application, see 37 CFR
1.63(c)(2) and 1.53(b).
- ☐ Application Data Sheet, See 37 CFR 1.76

- ☐ CD-ROM or CD-R in duplicate, large table or Computer Program (Appendix)
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 - Specification Sequence Listing on:
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ACCOMPANYING APPLICATION PARTS

- ☒ Assignment Papers (cover sheet & document(s))
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- ☐ English Translation Document (if applicable)
- ☒ Information Disclosure Statement (IDS)/PTO-1449 ☒ Copies of IDS Citations
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18. If a CONTINUING APPLICATION, check appropriate box, and supply the requisite information below and in the first sentence of the specification following the title, or in an Application Data Sheet under 37 CFR 1.76:

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No.:

Prior application information: Examiner: Art Unit:
For CONTINUATION OF DIVISIONAL APPS only, The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 5b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

19. CORRESPONDENCE ADDRESS

☒ Customer Number: 022874 OR ☐ Correspondence address below

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In re Application of

Date: October 22, 2003

Khalid Raja, et al.

Examiner: Unknown

Serial No.: Filed concurrently herewith

Art Unit: Unknown

Filed: Filed concurrently herewith

Attorney Docket No.: ACMI-2.006US

For: FLUID DELIVERY SYSTEM FOR
USE WITH A SURGICAL PUMPING UNIT

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Jessica Harvey
Date of Deposit: October 22, 2003

PRELIMINARY AMENDMENT

Sir:

Please amend the present application, which is being filed concurrently herewith, and is
the U.S. National Phase of PCT Application number PCT/US02/15729, filed May 16, 2002, and
is entitled "Fluid Delivery System For Use With A Surgical Pumping Unit", as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Drawings begin on page 4 of this paper.

Remarks/Arguments begin on page 5 of this paper.

An Appendix including amended drawing figures is attached following page 5.

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Amendments to the Specification

Please replace the paragraph on page 1, lines 8-11 with the following paragraph:

This invention is the U.S. National Phase of International Patent Application No. PCT/US02/15729, filed May 16, 2002, and claims the benefit of co-pending U.S. Provisional Application No. 60/291,583, entitled Fluid Delivery System For Use With A Surgical Pumping Unit, filed May 16, 2001, the entire disclosure of which is incorporated by reference as if set forth in its entirety for all purposes.

Please replace the paragraph on page 15, lines 8-14 with the following amended paragraph:

Instead of screw threads the pump may be connected to the L-bracket extension 340 by a bayonet-type lock as seen in ~~Fig. 35~~ Fig. 34. In this embodiment, spike 342 is connected to a top end of the impeller housing 344 by a press fit with an O-ring 346 providing a fluid seal. Impeller housing 344 is located within extension 340 so that spike 342 extends through an opening 348 for connection with a fluid bag. Impeller housing 344 is then rotated so that a protrusion 350 is received in a lock opening 352 in extension 340.

Please replace the paragraph on page 15, lines 19-26 with the following amended paragraph:

~~Figure 36~~ Figure 35 shows another embodiment in which a pump such as, for example, is directly connect to a fluid bag and is supported by a special fitting. An outer fitting 360 is securely attached to impeller housing 362 so that spike 364 extends through and out of outer fitting 360 for connection with a fluid bag. Outer fitting 360 includes an inner member 366 with gripping teeth 368 to frictionally grip the outside of fluid bag outlet 365 when spike 364 is attached thereto. In this embodiment, the pump is suspended from the fluid bag but is held by the frictional engagement between inner member 366 and the fluid bag outlet.

Please replace the paragraph beginning on page 15, line 27, extending to page 16, line 2, with the following amended paragraph:

~~Figure 37~~ Figure 36 shows another embodiment in which the pump is suspended from the fluid bag by a spike 380. However, fluid flow is not automatically started upon spiking the fluid bag. Spike 380 includes a valve lever 382 that is normally biased to a closed position by an extension spring 383. After spike 380 has been inserted into the fluid bag the fluid bag presses down on valve lever 382 against the bias of extension spring 383 to the position shown in phantom in Fig. 37 to open the fluid passageway in spike 380 to allow fluid to flow from the fluid bag. Fluid flow will only be facilitated when valve lever 382 is moved down by the fluid bag. When the fluid bag is removed valve lever 382 is closed by extension spring 383.

Please replace the paragraph beginning on page 16, lines 6-14, with the following amended paragraph:

COPY

Figure 40 Figure 39 shows an alternative embodiment of supporting the pump from a fluid bag 450. In this embodiment, spike 452 includes a retainer fan 454 that is retracted until spike 452 is inside fluid bag 450. Spike 452 has an outer diameter that is less than the inner diameter of fluid bag outlet 456 so that there is clearance between the walls of fluid bag outlet 456 and spike 452. In use, the user will spike fluid bag 450 while retainer fan 454 is retracted. After spiking fluid bag 450, retainer fan 454 is opened by an actuator 458 on impeller housing 460 459 so that retainer fan 454 moves up into fluid bag 450 and opens. Retainer fan 454 will be completely open when it passes fluid bag outlet 456. The user then releases the pump which will drop under its own weight so that retaining fan 454 can rest on the inside of fluid bag 450. The fluid bag outlet 456 includes a seal 462 460 to prevent fluid loss.

Figures 41 and 42 **Figures 40-41** show one embodiment for actuating retainer fan 454. Retainer fan 454 includes spring-biased arms 460 461 that are normally closed as seen in Fig. 42 **Fig. 41**. To open retainer fan 454 actuator 458 is moved to the left as shown in Fig. 42 **Fig. 41** so that bottom portion 462, which in the closed position rests on upper surface 464 of actuator 458, moves downward along surface 468 to rest on surface 466. As bottom portion moves arms 460 461 are biased open (Fig. 41) **(Fig. 40)** to rest or engage inner surface 470 of fluid bag 450.

Amendments to Drawings

COPY

Please replace the originally filed drawings with the drawings attached in the Appendix attached hereto.

Remarks/Arguments

The amendments to the specification correct minor errors.

The formal drawings replace the informal drawings as originally filed.

No new matter has been entered.

CONCLUSION

Applicant submits that in view of the foregoing arguments and/or amendments, the application is in condition for allowance, and favorable action is respectfully requested. The Commissioner is hereby authorized to charge any fees, including extension fees, which may be required, or credit any overpayments, to Deposit Account No. 50-1001.

Respectfully submitted,

Date: October 22, 2003

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